REMARKS/ARGUMENTS

The Pending Claims

Claims 1-17, 69, 70, and 78-85 are pending currently. Claims 1-17, 69, 70 and 78-82 are directed to a composition comprising particulate tricalcium phosphate (TCP) having an average particle size of about 5 μm or less, an average crystal size of about 250 nm or less and a surface area of about 20 m^2/g or greater, wherein when the particulate TCP that is densified to form an article having a minimum dimension of about 0.5 cm or greater the article transmits about 50% or more light having a wavelength in the range of about 150 nm to about 1,000 nm. Claims 83-85 are further directed to a composition comprising particulate TCP that is produced using a wet chemical approach, and wherein when the particulate TCP is densified to form an article having a minimum dimension of about 0.5 cm or greater the article has a density that is 90% of the theoretical density or greater.

Summary of the Office Action

Claims 1-7, 12-14, 17 and 69-70, 78 and 79 stand again rejected under 35 U.S.C. § 103(a) as allegedly obvious over Kawamura et al. (i.e., U.S. Patent 4,717,556) in view of Tanaka et al. (i.e., U.S. Patent 6,441,073). Claims 8-11 stand again rejected under 35 U.S.C. § 103(a) as allegedly obvious over Kawamura et al., Tanaka et al., and Kijima et al. (i.e., U.S. Patent 5,185,177). Claims 15 and 16 stand again rejected under 35 U.S.C. § 103(a) as obvious over Kawamura et al., Tanaka et al., and Dalal et al. (i.e., U.S. Patent 6,949,251). Claims 80-85 are rejected under 35 U.S.C. § 103(a) as obvious over Kawamura et al. in view of Tanaka et al.

The Obviousness Rejections

Applicants respectfully traverse the obviousness rejections.

(a) The Present Invention is Non-Obvious over Kawamura et al.

The present invention is directed toward a composition comprising particulate tricalcium phosphate (TCP) having (1) an average particle size of 5 μm or less, (2) an average crystal size of about 250 nm or less, and (3) a surface area of about 20 m^2/g or greater. The present invention, as further recited in independent claim 1, is directed towards a composition

comprising particulate TCP having all three aforementioned properties such that when the particulate TCP is densified to form an article having a minimum dimension of about 0.5 cm or greater the article transmits about 50% or more light having a wavelength in the range of about 150 nm to about 1,000 nm. Additionally, the present invention, as further recited in independent claim 83, is directed towards a composition comprising particulate TCP having all three aforementioned properties that is produced using a wet chemical approach, and wherein when the particulate TCP is densified to form an article having a minimum dimension of about 0.5 cm or greater the article has a density that is 90% of the theoretical density or greater.

Neither Kawamura et al. nor Tanaka et al., taken alone, disclose all three properties of (1) an average particle size of 5 μm or less, (2) an average crystal size of about 250 nm or less, and (3) a surface area of about 20 m^2/g or greater. Moreoever, neither Kawamura et al. nor Tanaka et al., taken alone or in combination, disclose densification of the TCP to form an article having a minimum dimension of about 0.5 cm or greater the article transmits about 50% or more light having a wavelength in the range of about 150 nm to about 1,000 nm. Instead, the Office Action relies on the combination of Kawamura et al. and Tanaka et al. to argue that the claimed invention is unpatentable. Specifically, the Office Action selects the surface area and crystal size from Kawamura et al., and the particle size from Tanaka et al., and asserts that a person of ordinary skill in the art would have been motivated to utilize the particle size taught in Tanaka et al. with the surface area and crystal size from Kawamura et al. to arrive at the claimed invention. Additionally, with respect to claim 1, the Office Action asserts that the transmittance of about 50% or more light having a wavelength in the range of about 150 nm to about 1,000 nm is inherent to the article that can be made according to the teachings of Kawamura et al. and Tanaka et al. However, the Office Action's assertions are erroneous for at least the following reasons.

First, a person of ordinary skill in the art would not have been motivated to utilize the particle size taught in Tanaka et al. in connection with the surface area and crystal size from Kawamura et al. to arrive at the claimed invention.

The present invention is based, in part, upon the discovery that minimizing crystal size makes consolidation of the crystals easier because smaller crystals can re-arrange and

pack more readily, and in turn, this agglomeration of crystals prior to densification serves to enhance densification. *See, e.g.,* ¶ [0022]. More specifically, Applicants discovered that improved densification occurs when the average particle size of the TCP approaches the average crystal size of the TCP. *See id.* This improved densification allows the article formed from the densified TCP, wherein the TCP comprises the claimed particle size, crystal size, and surface area, to transmit about 50% or more light having a wavelength in the range of about 150 nm to about 1,000 nm. Thus, the present invention is based, at least in part, upon the discovery that the size of *both* the particles and crystals affect densification, and hence, the ability of an article formed from the densified TCP to transmit about 50% or more light having a wavelength in the range of about 150 nm to about 1,000 nm.

While Kawamura et al. discloses crystal size, and while Tanaka et al. discloses particle size, neither reference teaches or suggests the interplay between these two properties of TCP. Thus, one of ordinary skill in the art, in view of the teachings of both Kawamura et al. and Tanaka et al., would not have thought that by reducing particle size in accordance with Tanaka et al., while maintaining the crystal size and surface area taught in Kawamura et al., densification would improve such that the resulting TCP powder could be densified to transmit about 50% or more light having a wavelength in the range of about 150 nm to about 1,000 nm.

Second, a person of ordinary skill in the art who sought to make a bioceramic material for use in implants, as in the case of the present invention, would not have been motivated to combine Kawamura et al. with Tanaka et al. to arrive at the present invention.

The present invention is directed towards a bioceramic material for use in implants. *See, e.g.,* ¶ [0002]. However, while Kawamura et al. also purports to be directed to a TCP powder suitable for use as a raw material for implants, Kawamura et al. was later recognized by its own inventors as being potentially biologically unsafe due to impurities such as non-reacted matter like $Ca(OH)_2$. *See* Hakamatsuka et al. (i.e., U.S. Patent No. 5,322,675) at col. 2, ll. 9-11. The invention disclosed in Hakamatsuka et al. was invented by, *inter alia*, Sukezo Kawamura and Motohiro Toriyama, the two named inventors of Kawamura et al. These two named inventors recognized a problem with the invention set forth in Kawamura et al.—namely, that the invention may cause hemolysis, antigenicity, and cytotoxicity. All of this

teaches against using the material disclosed in Kawamura et al. in a biological implant. *See, e.g.,* Hakamatsuka et al. at col. 2, ll. 22-27. Therefore, a person of ordinary skill in the art would have recognized the potential biological safety concerns associated with Kawamura et al. and would have avoided use of the teachings of Kawamura et al., either alone or in combination with any other reference including Tanaka et al., to arrive at the claimed invention.

Additionally, with respect to claim 83, Kawamura et al. and Tanaka et al. each fail to teach or suggest a particulate tricalcium phosphate composition produced using a *wet chemical* approach having the average particle size, average crystal size and surface area. Kawamura et al. is directed to a β-tricalcium phosphate prepared by a *mechanochemical* process involving preparing a slurry of hydrogen calcium phosphate and calcium carbonate powders in water and then subjecting that slurry to attrition (e.g., using a ball mill). *See* Abstract; col. 2, ll. 31-49; col. 3, ll. 29-43, and Example 1. Kawamura et al. contrasts this mechanochemical approach from a wet chemical approach, which it describes as suffering numerous disadvantages including low purity and poor crystal formation. *See* col. 1, ll. 46, to col. 2, ll. 12.

The deficiencies of Kawamura et al., both alone and in combination with Tanaka et al., are not cured by Kijima et al. or Dalal et al. with respect to the remaining claims because none of these references teach or suggest a particulate tricalcium phosphate composition having the average particle size, average crystal size, and surface area recited in the pending claims.

(b) The Present Invention is Non-Obvious over Hakamatsuka et al.

Hakamatsuka et al., taken in combination with Kawamura et al. and/or Tanaka et al., does not render the claimed invention obvious. While Applicants admit that Hakamatsuka et al. proclaims to be an improvement over Kawamura et al., as Hakamatsuka et al. claims to improve upon the biological safety of Kawamura et al., Hakamatsuka et al. makes no mention of particle size, surface area, or crystal size. Thus, a person of ordinary skill in the art would not read Hakamatsuka et al., either alone or in combination with Tanaka et al., as disclosing the claimed invention, which is directed towards a TCP that has a specific particle size, surface area, and crystal size.

It can not be assumed that the method disclosed by Hakamatsuka et al. will necessarily produce TCP having the the same crystal size and surface area as Kawamura et al., as Hakamatsuka et al. alters the process set forth in Kawamura et al. Hakamatsuka et al. modifies the process set forth in Kawamura et al. such that an aqueous slurry is prepared by using pure water of a particular temperature—30° C or higher. *See, e.g.,* col. 6, ll. 55-63. Hakamatsuka et al. hypothesizes that this particular temperature may lead to the preparation of a more homogenous calcium phosphate composition. *See id.* However, in addition to potentially creating a more homogeneous composition, the increase in slurry temperature may significantly impact the crystal size and surface area of the resulting composition. Thus, one of ordinary skill in the art would not arrive at the claimed crystal size, particle size, and surface area by merely combining the teachings of Hakamatsuka et al. with Tanaka et al. and/or Kawamura et al.

Also, one of ordinary skill in the art would not arrive at a composition of the purity claimed in the present invention, such that when the claimed particulate TCP is densified to form an article having a minimum dimension of about 0.5 cm or greater the article transmits about 50% or more light having a wavelength in the range of about 150 nm to about 1,000 nm. Hakamatsuka et al. uses an attrition milling process to obtain the calcium phosphate composition set forth therein. It is well-known in the art that attrition milling leads to impurities in the resulting milled composition. *See, e.g.,* F.F. Lange et al., "Effects of attrition milling and post-sintering heat treatment on fabrication, microstructure and properties of transformation toughened ZrO_2," *Journal of Materials Science*, 21:768-774 (1986) ("[I]mpurities introduced during attrition milling can be significant relative to the unmilled powder."); *see also* Declaration Under 37 C.F.R. § 1.132 of Edward S. Ahn, Ph.D ("Declaration of Ahn), submitted with the response to Office Action dated October 26, 2009. These impurities would undoubtedly impact the ability of the densified TCP to transmit light. *See* Declaration of Ahn. Thus, one would not arrive at the present invention, with the claimed purity, by following the teachings of Hakamatsuka et al. in combination with Tanaka et al.

The deficiencies of Kawamura et al., as modified by Hakamatsuka et al., both alone and in combination with Tanaka et al., are not cured by Kijima et al. or Dalal et al. with respect to the remaining claims because none of these references teach or suggest a

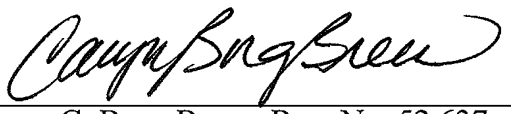
particulate tricalcium phosphate composition having the average particle size, average crystal size, and surface area recited in the pending claims.

In view of the foregoing, Applicants respectfully submit that the pending claims are not rendered obvious by the cited references.

Conclusion

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



Caryn C. Borg-Breen, Reg. No. 52,637
LEYDIG, VOIT & MAYER, LTD.
Two Prudential Plaza, Suite 4900
180 North Stetson Avenue
Chicago, Illinois 60601-6731
(312) 616-5600 (telephone)
(312) 616-5700 (facsimile)

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